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10/687,269	10/16/2003	John Gavin MacDonald	KCX-841 (19233)	9988

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
02/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,269	MACDONALD ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-10,12,14,17 and 19-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-10,12,14,17,21,23-31,33,34,36 and 39* is/are rejected.

7)☒ Claim(s) *8,9,19,20,22,32,35,37 and 38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 4-10, 12, 14, 17, and 19-39 are pending. Applicants previously cancelled claims 2-3, 11, 13, 15-16, and 18. Applicants have amended claims 1, 17, 31, and 33. Claims 35-39 are new. Applicants are advised that a different examiner is examining the instant application. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments.

Terminal Disclaimer(s)

The terminal disclaimer filed on 10/1/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of copending application 10/687,270 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

Claims 8-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Dependent claims 8-9 both directly depend from claim 1. Claims 8-9 are essentially verbatim copies of each other, because the phrases "has not been utilized" and "has been used" in reference to the odor absorbing capacity are semantically equivalent. Claims 8-9 recite that the indicating agent is applied in differing concentration in two or more zones to indicate how much of

the odor capacity of the article has not been utilized. Applicants amended claim 1 to recite "the visual indication agent being applied in differing concentrations in two or more zones." Thus, claims 8-9 do not further limit the claimed article of claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 10, 17, 25-30, 33-34, 36, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is indefinite because the following words/terms do not refer to odors, but rather to chemical compounds and/or elements: mercaptans, sulfide, hydrogen sulfide, amines, ammonia, sulfur, sulfur degradation products, aliphatic acids, isovaleric acid, butyric acid and acetic acid.

Claim 10 is also indefinite, because it is unclear to which degradation products of sulfur Applicants are referring. Sulfur is an element. Elements cannot be degraded into smaller chemical entities, absent nuclear degradation of the element by fission or other nuclear processes. Thus, the metes and bounds of the phrase "sulfur degradation products" are unclear.

Claims 36 and 39 are indefinite because said claims identify chlorite and persulfate as metal ions. Chlorite and persulfate are not metal ions, because these anions lack a metal atom. Chlorite has the chemical formula of OCl_2^- and persulfate has the

chemical formula of SO_5^-. Thus, the description of chlorite and persulfate as metal ions contradicts the well-accepted meaning of these terms and is repugnant to the art.

Claims 4, 17, and 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the change in color that is indicative of saturation of the article with the odor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under

37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-9, 12, 14, 17, 23-25, and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tratnyek (U.S. Patent No. 4,407,960) (of record), as evidenced by the June 1995 BOC Gases MSDS for ethylene oxide.

Applicant Claims

Applicants claim (1) an article for controlling odor comprising (a) a substrate including an odor controlling agent and at least one visual indicating agent applied in differing concentrations in two or more zones that is selected from a group including 4,4-bis(dimethylamino)-benzhydrol (i.e. Michler's hydrol); and (2) a method of visually indicating when an article for controlling odor is saturated.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Tratnyek teaches **clay-containing substrates, such as a coated boxboard, a coated paper cover stock, and a shiny coated paper stock, with ~0.1% w/w or 0.89% w/w of Michler's hydrol (i.e. 4,4'-bis(dimethylamino)-benzhydrol)** (Table II: Col. 12, lines 22-38). Clay is an odor absorbing material. In some embodiments, Tratanyek teaches a composition comprising Michler's hydrol, **silica**, and a polymeric binder (e.g. ethyl cellulose or styrene-maleic anhydride resin). (Id.) Tratanyek's system was developed as a visual indicator system in sterilization processes utilizing ethylene oxide

(Title; Abstract; Table 1). Tratanyek teaches that the system may be applied to any substrate, such as **silica or cellulose blotters** (col. 4, line 68 through col. 5, line 8). The inclusion of an acid component, such as, 4,4-bis(4-hydroxyphenyl)pentanoic acid enhances the observed color change (col. 5, lines 10-15). Tratanyek teaches the various color changes of the indicator system comprising Michler's hydrol that upon observation indicate saturation of the article with ethylene oxide (See Table 1, items 3-5).

Ethylene oxide is a slightly sweet-smelling gas (i.e. an odor), as evidenced by BOC Gases MSDS for ethylene oxide (prepared June 1, 1995) (see page 5 of 7, section 9: "Physical and Chemical Properties").

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Tratanyek lacks the teaching of an article containing two or more zones having differing concentrations of an indicator, selected from the group including Michler's hydrol. This deficiency is obvious as described below.

Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)

It would have been prima facie obvious to modify articles containing Tratanyek's visual indicator system to contain two or more zones of varying concentrations of the visual indicator, such as Michler's hydrol, to facilitate the detection of an endpoint of sterilization with ethylene oxide, wherein the chamber in which the indicator system may not be readily visible. A variation in concentration would facilitate the detection of adequate sterilization in hard-to-see places, as the resulting color change would be more

dramatic and easier to visually detect. An ordinary skilled artisan would have been motivated to utilize two or more visual indicator zones with differing indicator concentrations to ensure maximal sterilization efficiency and minimize costs incurred due to incomplete sterilization, such as infections if a medical instrument was not completely sterilized in a hard to see portion of the medical instrument. An ordinary skilled artisan would have had a reasonable expectation of success, because application of different concentrations to different regions of an article is well within the capability of the ordinary skilled artisan. Regarding claims reciting product-by-process limitations of claimed articles (e.g. Applicants' claims 6-7), these process limitations are not deemed to materially affect the structure of the claimed article and are given no patentable weight. It is the Examiner's position that coated paper stock reads on a disposable odor absorbing sheet. A sheet of paper also reads on a substrate in the form of a strip.

Regarding the claimed method, Tratanyek's, exemplified articles could only be prepared by the introduction of an indicator system. It is clear from Tratanyek's guidance (e.g. in Table I) that the observation of a color change is indicative of article saturation with ethylene oxide (i.e. an odor). Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Claims 1, 4, 6-10, 14, 17, 21, 27-29, 31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Springer et al. (US 2003/0130631) (of record) in view of Horan (U.S. Patent No. 6,149,952).

Applicant Claims

Applicants claim (1) an article for controlling odor comprising (a) a substrate including an odor controlling agent and at least one visual indicating agent applied in differing concentrations in two or more zones that is selected from a group including 4,4-bis(dimethylamino)-benzhydrol (i.e. Michler's hydrol); and (2) a method of visually indicating when an article for controlling odor is saturated.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Springer teaches a method and apparatus for detecting changes in pH in the interiors of articles, such as **diapers, incontinence garments, pads**, etc. (title; abstract; [0002]). Spring teaches that olfactory detection of toxic levels of ammonia in diapers is no longer reliable, due to the development of superabsorbent diaper materials. The human detection threshold for ammonia gas is 5-50 ppm, but diaper barriers can contain the ammonia odor within the diaper, frustrating detection ([0004]-[0005]). The longer a diaper is worn the faster ammonia is formed and the faster pH rises, which can create a local environment **promoting the growth of microbes** (e.g. bacteria), which can result in diaper dermatitis ([0007]-[0008], [0027], [0031], [0033]). Springer's apparatus/method utilizes a combination of a sensor/indicator to alert caregivers of the need to change a diaper via an observable color change [Fig. 2; [0038]-[0039]). Springer's apparatus includes a liquid permeable coversheet facing superimposed relation with the inner surface of a liquid impermeable coversheet and **an absorbent core**. An absorbent core reads on an odor absorbing material. Urine is transported to a chemically reactive means that includes a sensor that undergoes a color change to indicate pH (Id.). Several suitable

indicators are taught, including **alpha-naptholbenzein** ([0053]). Springer teaches a method comprising (i) applying a diaper having a means for indicating by visual color change the pH of the diaper interior to a subject, (ii) observing the color of the indicating means, and (iii) determining from the color change whether the diaper interior pH has reached an unsafe level. Because the pH changes detected by Springer's method are a consequence of the presence of ammonia dissolved in urine, Springer's method indirectly detects an odorous compound (i.e. ammonia).

Horan teaches a method for determining deleterious bacterial growth in packaged food, wherein a gas, such as CO, CO_2, hydrogen sulfide, sulfur dioxide, ammonia results in a color change in response to the presence of gases due to indicators dispersed throughout a polymeric matrix (Title; abstract; col. 1, lines 49-61). **Alpha-naptholbenzein is an exemplary indicator disclosed by Horan for the detection of gases evolved by bacteria, such as ammonia, hydrogen sulfide, or sulfur dioxide** (col. 7, lines 48-56). Horan teaches that the chemical response of the indicator is typically concentration dependent (col. 7, lines 31-32).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Springer lacks the teaching of an article with two or more zones of a visual indicator at different concentrations. This deficiency is cured by the teachings of Horan.

Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)

It would have been prima facie obvious to combine the teachings of Springer and Horan, because both references attempt to solve the problem of detecting gases produced by bacteria, which are indicative of other problems, such as deleterious side effects to diaper wearers (Springer) or the presence of pathogenic bacteria (Horan). Both references also identify bacteria as a source of the gases that are detected. Springer focuses on the use of a visual detection system responsive to pH changes caused by ammonia, whereas Horan focuses on the detection of gases that undergo a chemical reaction with a visual indicator to induce a color change that would indicate the presence of pathogenic bacteria. Both references recognize that color changes are suitable means to alert users of a given product of the presence of odor compounds (e.g. ammonia), which are indicative of other problematic circumstances (e.g. dangerous diaper pH levels or pathogenic bacteria). Thus, an ordinary skilled artisan would have been motivated to combine the cited references, because both references address the same problem: detection of gases via a visual indicator system. An ordinary skilled artisan per the teachings of Horan would recognize that the alpha-naptholbenzein identified as a suitable indicator by Springer to detect the presence of ammonia and harmful pH changes in a diaper would also be suitable to detect the presence of malodorous compounds such as hydrogen sulfide and sulfur dioxide. Furthermore, an ordinary skilled artisan cognizant of Horan's teaching that the indicator chemical reaction leading to the visual color change is concentration dependent would be motivated to utilize varying concentrations of a particular indicator on an article to ensure that the presence of a malodorous gas would be detected by users of the article and/or caregivers. An ordinary skilled artisan would have had a reasonable expectation of successfully detecting odorous compounds

such as ammonia, hydrogen sulfide, and sulfur dioxide upon combination of Springer's invented diaper apparatus and Horan's teachings, because both references identify alpha-naptholbenzein as a suitable visual indicator.

Regarding the amount of naptholbenzein utilized in Springer's diaper, Springer is silent. However, because Horan teaches that the indicator-gas chemical reaction is concentration dependent, an ordinary skilled artisan would have been motivated to modulate the amount of the visual indicator present on the article and its concentration on the article to obtain the desired result of an article exhibiting a color change due to the presence of ammonia and other gaseous products of bacteria reasonably expected to cause dangerous pH changes in a diaper interior (e.g. ammonia, sulfur dioxide, etc.). Regarding claims reciting product-by-process limitations of claimed articles (e.g. Applicants' claims 6-7), these process limitations are not deemed to materially affect the structure of the claimed article and are given no patentable weight. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claim 8 be found allowable, claim 9 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 8-9 have been described supra in the "claim objection" section.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 20-21 of copending Application No. 10/790,617 (copending '617). Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim articles (e.g. a device) containing two or more detection or indicator zones comprising the same indicators, wherein the indicators also act to absorb some odor. The primary difference between claim 1 of the instant application and the cited claims of copending '671 is the recited intended use of the two articles. The article of the instant application is recited as being intended to control odors, whereas the assay device of copending '617 is described as being for the detection of the presence or absence of amines. Amines are odorous compounds, as admitted by Applicants (see Applicants' claim 10). A device is necessarily an article. Thus, the recited intended use of the article of the instant application and copending '617 represent obvious variants, because to detect an amine the device of copending '671 would be required to absorb or adsorb amine molecules, resulting in some finite odor control.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 5-7, and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-5 and 7-9 of copending Application No. 12/134,547 (copending '547). Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim articles (e.g. device) containing an indicator zone

comprising the same indicators, wherein the indicators also act to absorb some odor. The primary difference between claims of the instant application and the cited claims of copending '547 is the recited intended use of the two articles. A device is necessarily an article. For the breath testing device of copending '547 to function properly, it would necessarily require the absorption or adsorption of the odorous compounds causing bad breath, and would necessarily result in some finite odor control.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claims 19-20, 22, 32, 35, and 37-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or fairly suggest article substrates comprising (i) odor absorbing agents, (ii) ***nanoparticles*** and (iii) a visual indicating agent selected from the group consisting of 4,4-bis(dimethylamino)-benzhydrol (i.e. Michler's hydrol), pararosaniline, alpha-naptholbenzein, and napthochrome green, wherein the indicator is present in two or more zones at differing compositions.

Conclusion

Claims 1, 4-10, 12, 14, 17, 21, 23-31, 33-34, 36, and 39 are rejected. Claims 8-9, 19-20, 22, 32, 35, and 37-38 are objected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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